Toxics Use Reduction Institute

POLICY ANALYSIS

September 21, 2009

Lower Hazard Toxic Substance Designation Recommendation:
Butyl Acetate (123-86-4) and Isobutyl Acetate (110-19-0)

The TURA Science Advisory Board (SAB) has recommended designating butyl acetate and isobutyl acetate as lower hazard toxic substances under TURA. With this designation, the per substance toxics use fee for these three substances would be eliminated. Facilities in TURA-regulated SIC codes using these substances above the reporting threshold would continue to report chemical use and pay the facility base fee annually, and to prepare TUR plans every two years.

This policy analysis summarizes the scientific information considered by the SAB, considers the number of facilities that are likely to be affected by this change, reviews the regulatory context, and discusses the implications of this policy measure for the TURA program. Based on this analysis, the Toxics Use Reduction Institute supports the SAB's recommendation that butyl acetate and isobutyl acetate be designated as lower hazard toxic substances.

The goal of designating a substance in the lower hazard toxic substance category is to indicate it is less hazardous than other TURA-listed substances. Since all substances listed under TURA are hazardous, this designation does not indicate a lack of basis for concern. As with all substances listed under TURA, facilities should work to reduce or eliminate the use of lower hazard toxic substances.

1. State of the Science

Butyl and isobutyl acetate are considered together in this policy analysis because they are similar in chemical structure and health and environmental effects. The principal hazards associated with these substances are neurotoxicity; eye, skin and respiratory irritation; and flammability. For a list of specific data examined by the Science Advisory Board in developing its recommendation, see Appendix A.

Butyl acetate and isobutyl acetate are colorless, flammable liquids with a fruity odor. They are widely used volatile organic solvents with moderate vapor pressure. They are used as solvents in inks, coatings, finishes, thinners, fragrances and cosmetics.[1]

Acute toxicity

- As organic solvents, both chemicals are neurotoxicants. Acute effects of exposure to butyl or isobutyl acetate include adverse effects on the central nervous system, including headache, muscle weakness, giddiness, loss of coordination, confusion, delirium, and coma; gastrointestinal effects, including nausea, vomiting, or diarrhea; skin, eye, and throat irritation; difficulty breathing; and heart arrhythmias.[2]
- Both butyl acetates have a lower vapor pressure (less volatile) compared with many other volatile organic solvents.
- The LD_{50} values for butyl acetate and isobutyl acetate are 14,000 mg/kg (oral rat) and 4,800 mg/kg (oral rabbit), respectively, indicating relatively low acute toxicity.

- The OSHA permissible exposure limits (PELs) for butyl acetate and isobutyl acetate are both150 ppm. These relatively low occupational exposure limits are based on data showing eye, skin and respiratory irritant effects in humans.[3]

Chronic toxicity

- Chronic effects of exposure to large amounts of butyl acetate or isobutyl acetate include chronic solvent encephalopathy, CNS Solvent Syndrome or "chronic painters' syndrome," characterized by mood changes, and impairment of cognitive function.[4]
- The International Agency for Research on Cancer (IARC) does not list butyl acetate or isobutyl acetate as carcinogens.
- Neither of the butyl acetates are listed on California's Proposition 65 list of reproductive or developmental toxicants.

Environment

- Both chemicals have relatively low persistence in water, soil and sediment and are unlikely to bioaccumulate.
- The chronic fish toxicity values for the three chemicals are 10 mg/L and 9 mg/L respectively, indicating medium-low aquatic toxicity.

Safety

Both substances are Class 1B flammable liquids.[5]

Uncertainty

The hazards of both substances are relatively well understood. Uncertainty does not play a significant role in development of our policy recommendations in this case.

2. Facilities Affected

According to the 2007 TURA data, 8 facilities report for butyl acetate and 2 facilities report for isobutyl acetate. These facilities are in various SIC codes, most commonly 2851 (Paints and Allied Products). Thus, a total of 10 facilities would be affected by designating the butyl acetates as lower hazard substances.

Butyl and Isobutyl acetate are potential substitutes for more hazardous organic solvents. While still being toxic and hazardous, they are less volatile, less toxic and have a lower flash point than many other commonly used organic solvents.

3. Regulatory Context

Both substances are regulated under several statutes at the federal level. However, they are not targeted as priorities at the federal or state level.

EPCRA	• Butyl and isobutyl acetate: not reportable under TRI.[6]
CAA	• Not listed as Hazardous Air

	Pollutants[7]
CERCLA	• Butyl acetate and isobutyl acetate: Facilities required to notify National Response Center if release ≥ 5,000 lb.[8]
OSHA PEL	• Butyl acetate: 150 ppm • isobutyl acetate: 150 ppm
SDWA	• Not regulated as drinking water contaminants[9]
FDA	• Permitted as a food additive under certain circumstances[10]

International

- In Canada's Domestic Substance List categorization, isobutyl acetate meets the Government of Canada Categorization Criteria, while butyl acetate does not. These categorization criteria indicate that there is a basis for concern, such that further attention to the chemical is required, based on one of the following metrics: persistence, bioaccumulation, inherent toxicity to humans or non-human organisms, or potential for high exposures.[11] Isobutyl acetate met the categorization criteria for potential for high exposures.

4. Implications for the TURA program

Designation of butyl acetate and isobutyl acetate as lower hazard substances would mean facilities no longer would be required to pay the per-substance toxics use fee of $1,100 for these substances. Based on 2007 reporting data (10 reports for these substances, including at least one distributer for which the fee would not change due to the maximum rule), the total revenue loss to the TURA program would not exceed $9,900[12]. Companies would continue to report and plan for these chemicals, so the program would still receive reporting data and the companies would still gain the benefits of planning.

Appendix A: Information Considered by the SAB

Butyl Acetate (123-86-4)

International Agency for Research on Cancer (IARC)	not listed
PBT Profiler:	
Half life in water	8.7 days
Half life in soil	17 days
Half life in sediment	78 days
Half life in air	3.3 days
Bioconcentration factor	4.7
Chronic Fish (ChV)	9 mg/L
LD50	14,000 mg/kg (oral rat)
Reference Dose	Not available
Flash Point	73 F

Isobutyl Acetate (110-19-0)

International Agency for Research on Cancer (IARC)	not listed
PBT Profiler:	
Half life in water	15 days
Half life in soil	30 days
Half life in sediment	140 days
Half life in air	2.9 days
Bioconcentration factor	4.7
Chronic Fish (ChV)	10 mg/L
LD50	4,800 mg/kg (oral rabbit)
Reference Dose	Not available
Flash Point	64 F

Appendix B: Glossary of Regulatory Terms

ACGIH	American Conference of Governmental Industrial Hygienists
CAA	Clean Air Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CWA	Clean Water Act
EPCRA	Emergency Planning and Community Right to Know Act
FDA	Food and Drug Administration
MCL	Maximum Contaminant Level
NIOSH	National Institutes of Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
RCRA	Resource Conservation and Recovery Act
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act

Tier II	Chemical inventory reporting requirements for facilities subject to EPCRA
TRI	Toxic Release Inventory
TWA-PEL	Time-weighted average - Permissible Exposure Limit
TWA-REL	Time-weighted average – Recommended Exposure Limit
TWA-TLV	Time-weighted average - Threshold Limit Value

[1] Dow Chemical Product Safety Assessment Isobutyl Acetate, Nov 5, 2008, accessed at http://www.dow.com/PublishedLiterature/dh_01aa/0901b803801aa372.pdf?filepath=productsafety/pdfs/noreg/233-00418.pdf&fromPage=GetDoc
Dow Chemical Product Safety Assessment n-Butyl Acetate, Nov 5, 2008, accessed at http://www.dow.com/PublishedLiterature/dh_01aa/0901b803801aa36e.pdf?filepath=productsafety/pdfs/noreg/233-00414.pdf&fromPage=GetDoc

[2] R.E. Gosselin, R.P. Smith, H.C. Hodge. *Clinical Toxicology of Commercial Products* 5th ed. Baltimore: Williams and Wilkins, 1984, summarized in Hazardous Substances Data Bank, available at http://toxnet.nlm.nih.gov/ (search by chemical name) , viewed September 2009.

[3] American Conference of Governmental Industrial Hygienists (ACGIH), *Documentation of the Threshold Limit Values and Biological Exposure Indices*, 7th edition, 2001..

[4] National Library of Medicine, HazMap: Occupational Exposure to Hazardous Agents, http://toxnet.nlm.nih.gov/ (search by chemical name). List of agents that cause CNS solvent syndrome, available at http://hazmap.nlm.nih.gov/cgi-bin/hazmap_adveff?form=adveff&Ag_Neurotoxin=4; description of chronic solvent encephalopathy available at http://hazmap.nlm.nih.gov/cgi-bin/hazmap_generic?tbl=TblDiseases&id=325, viewed January 2008.

[5] NIOSH Pocket Guide

[6] United States Environmental Protection Agency, Toxics Release Inventory, www.epa.gov/tri/chemical/RY2005ChemicalLists

[7] United States Environmental Protection Agency, Technology Transfer Network, Air Toxics Website, "The Clean Air Act Amendments of 1990 List of Hazardous Air Pollutants," available at http://www.epa.gov/ttn/atw/orig189.html.

[8] 40 CFR 302.4, summarized in Hazardous Substances Data Bank (HSDB), http://toxnet.nlm.nih.gov.

[9] US EPA, "Drinking Water Contaminants: Organic Chemicals," available at http://www.epa.gov/safewater/contaminants/index.html#organic, viewed September 2009.

[10] 21 CFR 172.515, summarized in Hazardous Substances Data Bank (HSDB), http://toxnet.nlm.nih.gov.

[11] CEPA Environmental Registry: Substances Lists, available at http://www.ec.gc.ca/CEPARegistry/subs_list/dsl/dslsearch.cfm, viewed January 2008. For information on the categorization criteria, see Environment Canada, "Human Health and the Canadian Environmental Protection Act, 1999," available at http://www.ec.gc.ca/CEPARegistry/gene_info/factsheets/fs_fi-health-sante.cfm. Chemicals that meet the categorization criteria pose a concern on at least one of the following metrics: persistence, bioaccumulation, inherent toxicity, or high potential for exposure. Iso-butyl acetate met the Human Health Categorization Criteria, because of great potential for human exposure.

[12] Facilities pay a per-chemical fee for each chemical, until the maximum fee for their facility size is reached. If a facility reports on a greater number of substances than that required to reach their maximum fee, they would not realize a fee reduction for using a lower hazard substance.